

December 22, 2000

2240 '00 DEC 26 A10 :06

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Ladies and Gentlemen:

RE: Docket No. 00N-1567

Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

Pursuant to the above-named proposed rule that was published in a *Federal Register* notice dated November 2, 2000 (Vol. 65, No. 213), the Agency is urged to consider simplifying the process to register manufacturers and list drugs in commercial distribution.

With respect to whether the proposed collection of information is necessary for the proper performance of FDA's functions, we are proposing that new products be reported on Form FDA 2657 only upon approval of the NDA or BLA. Thereafter, labeling changes reported in an Annual Product Report to each reviewing division and advertising samples submitted to DDMAC should satisfy FDA's requirement for updated product information.

Under Secs. 207.21 and 207.22, establishments must register with FDA by submitting Form FDA 2656. However, the establishment registration cannot be submitted without a drug product listing, and a drug product listing cannot be submitted without an approved NDA or BLA, resulting in the initial drug product listing being submitted without a labeler code. This can cause lengthy detention problems for products imported to the US which are frequently detained for lack of proper drug listing. It is, therefore, recommended that establishments be permitted to register their sites in anticipation of NDA or BLA approval so that a labeler code can be obtained prior to approval.

Respectfully submitted,

Hoffmann-La Roche Inc.



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ESM:eh

HLR No. 2000-3218

00N-1567

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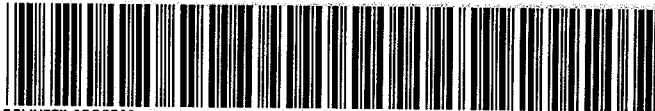
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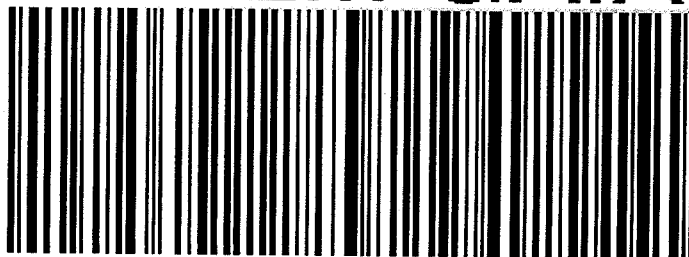
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